EXHIBIT B

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PAR PHARMACEUTICAL, INC., PAR STERILE PRODUCTS, LLC, and ENDO PAR INNOVATION COMPANY, LLC,	)	
Plaintiffs,	)	C.A. No. 18-823-CFC-JLH
v.	)	[redacted]
EAGLE PHARMACEUTICALS INC.,	)	
Defendant.	)	

LETTER TO THE HONORABLE COLM F. CONNOLLY
FROM BINDU A. PALAPURA

OF COUNSEL:

Jay P. Lefkowitz, P.C.
Jeanna M. Wacker
Benjamin A. Lasky
Sam Kwon
Christopher J. Citro
Matthew Lembo
KIRKLAND & ELLIS LLP
601 Lexington Avenue
New York, NY 10022
Tel: (212) 446-4800

Bryan S. Hales
KIRKLAND & ELLIS LLP
300 North LaSalle
Chicago, IL 60654
Tel: (312) 862-2000

Dated: June 8, 2021
7221531/ 45185

David E. Moore (#3983)
Bindu A. Palapura (#5370)
Stephanie E. O'Byrne (#4446)
POTTER ANDERSON & CORROON LLP
Hercules Plaza, 6th Floor
1313 N. Market Street
Wilmington, DE 19801
Tel: (302) 984-6000
dmoore@potteranderson.com
bpalapura@potteranderson.com
sobyrne@potteranderson.com

Attorneys for Defendant Eagle Pharmaceuticals Inc.

Potter Anderson Corroon LLP

1313 North Market Street
P.O. Box 951
Wilmington, DE 19801- 0951
302 984 6000
www.potteranderson.com

Bindu A. Palapura
Partner
Attorney at Law
bpalapura@potteranderson.com
302 984-6092 Direct Phone
302 658-1192 Firm Fax

June 8, 2021

VIA ELECTRONIC FILING
The Honorable Colm F. Connolly
United States District Judge
J. Caleb Boggs Federal Building
844 N. King Street
Unit 31, Room 4124
Wilmington, DE 19801-3555

[redacted]

Re: *Par Pharm., Inc. v. Eagle Pharm., Inc.*, C.A. No. 18-823-CFC

Dear Judge Connolly:

This firm, together with Kirkland & Ellis LLP, represents Defendant Eagle in the above-captioned matter. We write to apprise the Court of the parties' efforts to reach an agreement with respect to the proposed scope of the trial scheduled to commence on July 7. (May 26, 2021 Minute Entry).

Eagle's Proposal

As suggested during the May 26 teleconference (5/26/2021 Hearing Tr. at 27:11–28:5, 29:11–30:2, 30:19–22), to keep the July 7 trial date, Eagle has offered to stipulate that its proposed ANDA product will satisfy all of the claim elements except the pH limitations, reducing the infringement dispute to a single issue.[1]

Eagle submits that the trial should proceed on July 7 on this basis. Despite a history of doing so, Par did not raise any concern over the July 7 trial in its May 24 submission. (D.I. 245). Par does not dispute that Eagle may secure approval before year-end. (*See* 5/26/2021 Hearing Tr. at 22:5–23:20). Nor did Par argue that Eagle

[1] Eagle would limit its denial of induced infringement to not inducing others to practice the claimed method with a vasopressin formulation having the required pH.

will need to make changes to its pH specifications and pH-related manufacturing processes, in order to secure approval. (*See* D.I. 245; 5/26/2021 Hearing Tr. at 23:21–24:12). To the contrary, Par's counsel acknowledged that it "wouldn't be wasteful to go forward" in July on the issue of pH. (5/26/2021 Hearing Tr. at 23:21–24:12). There is no question that invalidity and unenforceability are ready for trial. Moreover, infringement and validity/enforceability should preferably be tried together so the Court can evaluate the tension between Par's positions on these issues. Eagle intends to show at trial that [redacted] by Eagle's proposed ANDA product.

Another trial delay would prejudice Eagle's ability to make an informed decision of an at-risk launch, and initiate any necessary preparations with its supply-chain to launch once it achieves FDA approval.[2]

Par's Proposal

Despite acknowledging that Eagle's proposal "would certainly help" and "would make it a shorter trial as well," (5/26/2021 Hearing Tr. at 28:12–13), Par has since rejected it. As we understand, Par will not agree to a July 7 trial unless Eagle drops its entire invalidity and unenforceability case, and the parties proceed only on the issue of *infringement*. For starters, there is zero basis for Par to ask Eagle to *drop* its validity and unenforceability challenges in order to proceed on infringement. It also makes no sense. [redacted] Par's

[2] The public will benefit as well. Vasopressin has been sold since the 1920s—before institution of the FDA drug approval process—and is used to treat critically ill patients, including those with COVID-19. In 2011, to encourage manufacturers to submit old drugs for approval, the FDA agreed to remove unapproved versions from the market if one were granted approval. *See* 4 CPG Sec. 440.100 at 5, https://www.fda.gov/media/72007/download. Par filed an application based on pre-existing literature, and no new clinical work, and received FDA approval for vasopressin using this process in 2014. Par then raised the price of vasopressin by over 1,500% after its competitors were removed from the market – despite the market having been generic for over 70 years. *See, e.g.*, Harris Meyer, *FDA Seeks a New Way to Review Old Drugs Without Causing Prices to Soar* (April 15, 2021), https://khn.org/news/article/the-fda-seeks-a-new-way-to-review-old-drugs-without-causing-prices-to-soar/.

insistence that Eagle drop issues that will not be impacted by ANDA changes reveals that Par's true motivation is just to avoid trial.

Those are not the only problems with Par's proposal. [redacted] when the Court indicated its schedule is even more crowded. As Eagle understands, Par proposes to alleviate that burden by offering to consent to Magistrate Judge Hall overseeing preliminary injunction proceedings if needed. This tactical proposal makes things worse, not better. As the Court will recall, Par would not—and still will not—consent to Magistrate Judge Hall for the trial itself. Your Honor will therefore still need to conduct the merits trial, meaning that Magistrate Judge Hall would needlessly expend energies familiarizing herself with a case that would ultimately be heard by Your Honor. And since Eagle may need to decide whether to launch at-risk if it prevails at the preliminary injunction stage, it is valuable and appropriate for the same judge to handle both proceedings. Eagle would still consent to trial before Magistrate Judge Hall, but believes the judge hearing preliminary injunction proceedings, if any, should be the same judge that hears the merits case.

Par vs. Amneal Considerations

[redacted] With respect, Eagle cannot agree to such an approach. ANDAs are multi-thousand-page, living documents that are routinely changed both before and after approval, sometimes at the insistence of the FDA.[3] Minor changes that have nothing to do with pH would result in Eagle having agreed that it infringes. By way of example, changing the vial capping process, source of rubber stoppers, or impurities specifications in the slightest would mean Eagle infringes, even though the product itself did not change and the pH is too low to fall within the claimed range. Even attempting to craft a narrower stipulation limited only to changes to Eagle's ANDA that impact pH would be unworkable, because Par could try to argue that non-pH changes *might* still impact pH. A change that maintains the pH of Eagle's ANDA product outside of the claimed range, or

[3] For example, Par amended its NDA as recently as 2019, years after its initial approval. (*See, e.g.*, PAR-VASO_0230785).

even takes it further away from the claimed pH range, could lead to infringement under the stipulation.

For these reasons, Eagle respectfully requests that trial proceed on July 7 as scheduled, and with Eagle's proposed stipulation.

Respectfully,

/s/ Bindu A. Palapura

Bindu A. Palapura

BAP/mas/7221531/45185

cc: Clerk of the Court (via hand delivery)
Counsel of Record (via electronic mail)